

## REMARKS

The above amendments and these remarks are responsive to the final Office action dated June 28, 2006. Claims 1-11, 13-21, 23, 24 and 26-28 are pending in the application. Claims 1-11, 13-21, 23, 24 and 26-28 are rejected. By way of the present amendment, claims 1, 11 and 18 have been amended, and claims 21 and 24 have been canceled. In view of the amendments above, and the remarks below, Applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

### *Rejections under 35 U.S.C. §§ 102 and 103*

Claims 1-6, 8-11, 14-18, 21, 23 and 24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Nash et al. (U.S. Pat. No. 6,709,427). Claims 7 and 13, which respectively depend from claims 1 and 11, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nash et al. in view of Glines et al. (U.S. Pat. No. 6,716,190). Claims 19, 20, and 26-28, which depend directly or indirectly from claims 1 and 18, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nash et al. in view of Kollias et al. (U.S. Pat. No. 6,251,099). Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention.

*Claim 1 and its Dependent Claims*

Amended claim 1 recites a needle-free jet injection device that includes, amongst other structure, an end effector that (1) is rigid, (2) has a blunt distal end, and (3) is “adapted to be positioned within a prostatic section of a patient’s urethra adjacent the patient’s prostate gland.” Further, as is apparent from the language of amended claim 1, an end effector that has a blunt distal end and is adapted to be positioned adjacent the patient’s prostate gland does not itself actually penetrate the prostate gland. Rather, as recited in amended claim 1, only the fluid ejected from the end effector actually “penetrate[s] the prostate gland,” not the end effector itself.

In contrast, Nash et al. does not disclose, teach, or suggest an end effector that is both rigid and has a blunt distal end, as recited in amended claim 1. Rather, Nash et al. discloses only fluid delivery instruments that are either both rigid and pierce the tissue being treated (i.e., are not blunt) or fluid delivery instruments intended for intravascular use, which are flexible and have blunt distal ends. In particular, the rigid fluid delivery instrument 200 shown in Fig. 7 of Nash et al. does not have a blunt distal end. Instead, the rigid fluid delivery instrument 200 of Nash et al. includes a distal end that is pointed to form a piercing member (col. 23, lines 44-45) such that the instrument may penetrate the myocardium (col. 23, lines 25-27, and shown in Fig. 7). Concurrently, the fluid delivery instruments disclosed in Nash et al. that do have a blunt distal end, such as those shown in Figs. 8 and 14, are not rigid. Instead, the fluid delivery devices 300 that are

shown in Figs. 8 and 14 of Nash et al. are “flexible pressurized intravascular access delivery instrument[s]” (see col. 12, lines 49-54, col. 13 lines 17-22, and col. 28, lines 62-67). Accordingly, Nash et al. does not disclose, teach, or suggest an end effector that is both rigid and has a blunt distal end.

Furthermore, contrary to the Examiner’s assertion on page 2 of the final Office action that the end effector is “capable of being positioned within the prostate gland,” amended claim 1 actually recites a rigid end effector that has a blunt distal end and is “adapted to be positioned within a prostatic section of a patient’s urethra adjacent the patient’s prostate gland.” Applicant respectfully asserts that a blunt rigid end effector, which is adapted to be positioned within a prostatic section of a patient’s urethra adjacent the patient’s prostate gland, as recited in amended claim 1, is not “capable of being positioned within the prostate gland,” as stated by the Examiner. This is in sharp contrast to the rigid fluid delivery instrument disclosed in Fig. 7 of Nash et al., which is clearly capable of being positioned within the prostate gland because the rigid fluid delivery instrument of Nash et al. has a distal end that is pointed to form a piercing member.

For at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2-10, 21, and 23 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited

art, and Applicant respectfully requests that the rejections of claims 1-10, 23 and 26 under 35 U.S.C. §§ 102 and 103 be withdrawn.

*Claim 11 and its Dependent Claims*

Amended claim 11 recites a needle-free jet injection device that includes, amongst other structure, an extension structure that (1) is longitudinally rigid, (2) includes a distal region that has a blunt distal end, and (3) is “adapted to be inserted within a patient’s urethra so that a distal region of the extension structure is positioned adjacent the patient’s prostate gland.” Further, as is apparent from the language of amended claim 11, an extension structure that includes a distal region that has a blunt distal end and is adapted to be inserted within a patient’s urethra so that a distal region of the extension structure is positioned adjacent the patient’s prostate gland does not itself actually penetrate the prostate gland. Rather, as recited in amended claim 11, only the fluid ejected from the extension structure actually “penetrate[s] the prostate gland,” not the extension structure itself.

In contrast, as discussed above, Nash et al. does not disclose, teach, or suggest an extension structure that is both rigid and includes a distal region that has a blunt distal end, as recited in amended claim 11. Furthermore, contrary to the Examiner’s assertion on page 2 of the final Office action regarding the capability of being positioned within the prostate gland, the extension structure recited in amended claim 11 is not “capable of being positioned within the prostate gland” because the extension structure is

longitudinally rigid, has a blunt distal end, and is “adapted to be inserted within a patient’s urethra so that a distal region of the extension structure is positioned adjacent the patient’s prostate gland.”

Thus, for at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 11. Claims 13-17 contain further limitations that distinguish the cited references. Accordingly, amended claim 11 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 13-17 under 35 U.S.C. §§ 102 and 103 be withdrawn.

*Claim 18 and its Dependent Claims*

Amended claim 18 recites a needle-free jet injection device that includes, amongst other structure, an end effector that (1) is rigid, (2) has a blunt distal end, and (3) is “adapted to be positioned with the injection orifice adjacent the selected internal tissue.” Further, as is apparent from the language of amended claim 18, an end effector that has a blunt distal end and is adapted to be positioned with the injection orifice adjacent the selected internal tissue does not itself actually penetrate the selected internal tissue. Rather, as recited in amended claim 18, only the fluid ejected from the end effector actually “penetrate[s] the selected internal tissue,” not the end effector itself.

In contrast, as discussed above, Nash et al. does not disclose, teach, or suggest an end effector that is both rigid and has a blunt distal end, as recited in amended claim 18.

Furthermore, contrary to the Examiner's assertion on page 2 of the final Office action, the end effector recited in amended claim 18 is not "capable of being positioned within" the selected internal tissue because the end effector is rigid, has a blunt distal end, and is "adapted to be positioned with the injection orifice adjacent the selected internal tissue." This is in sharp contrast to the rigid fluid delivery instrument disclosed in Fig. 7 of Nash et al., which is clearly capable of being positioned within the selected internal tissue because the rigid fluid delivery instrument of Nash et al. has a distal end that is pointed to form a piercing member, which may penetrate the selected tissue, as shown in Fig. 7.

Thus, for at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 18. Claims 19-20 and 27-28 contain further limitations that distinguish the cited references. Accordingly, amended claim 18 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 19-20 and 27-28 under 35 U.S.C. §§ 102 and 103 be withdrawn.

### **Conclusion**

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, Applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.

**CERTIFICATE OF MAILING**

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